



Rep. David Harris

Filed: 3/11/2015

09900HB3519ham001

LRB099 09712 AMC 32139 a

1 AMENDMENT TO HOUSE BILL 3519

2 AMENDMENT NO. _____. Amend House Bill 3519 by replacing
3 everything after the enacting clause with the following:

4 "Section 5. The Pharmacy Practice Act is amended by adding
5 Section 19.5 as follows:

6 (225 ILCS 85/19.5 new)

7 Sec. 19.5. Biological products.

8 (a) For the purposes of this Section:

9 "Biological product" means a biological product as defined
10 in subsection (i) of Section 351 of the federal Public Health
11 Service Act (42 U.S.C. 262(i)).

12 "Interchangeable" means a biological product that is
13 licensed by the United States Food and Drug Administration
14 pursuant to 42 U.S.C. 262(k)(4) or is deemed therapeutically
15 equivalent to another biological product by the United States
16 Food and Drug Administration and appears in the latest edition

1 or supplement of the Approved Drug Products with Therapeutic
2 Equivalence Evaluations (Orange Book).

3 "Prescription", with respect to a biological product,
4 means a product that is subject to Section 503(b) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

6 (b) A pharmacist may substitute a prescription biological
7 product for a prescribed biological product only if:

8 (1) the substituted product has been determined by the
9 United States Food and Drug Administration to be
10 interchangeable, as defined in subsection (a) of this
11 Section, with the prescribed biological product;

12 (2) the prescribing physician does not designate
13 orally, in writing, or electronically that substitution is
14 prohibited in a manner consistent with Section 25 of this
15 Act;

16 (3) the pharmacy informs the patient of the
17 substitution; and

18 (4) the cost of the substituted biological product is
19 less than the cost of the prescribed biological product or,
20 if the cost of the substituted biological product is more
21 than cost of the prescribed biological product, the patient
22 is informed and has agreed to accept the higher cost
23 substituted biological product.

24 (c) Within a reasonable time following the dispensing of a
25 biological product, the dispensing pharmacist or the
26 pharmacist's designee shall communicate to the prescriber the

1 specific product provided to the patient, including the name of
2 the product and the manufacturer. The communication shall be
3 conveyed by making an entry into an interoperable electronic
4 medical records system or through electronic prescribing
5 technology or a pharmacy record that is electronically
6 accessible by the prescriber. Otherwise, the pharmacist shall
7 communicate the biologic product dispensed to the prescriber
8 using facsimile, telephone, electronic transmission, or other
9 prevailing means, provided that communication shall not be
10 required where:

11 (1) there is no FDA-approved interchangeable
12 biological product for the product prescribed; or

13 (2) a refill prescription is not changed from the
14 product dispensed on the prior filling of the prescription.

15 (d) The pharmacy shall retain a record of the biological
16 product dispensed for a period of 5 years.

17 (e) The Board shall maintain a link on the Department's
18 Internet website to the current list of all biological products
19 determined by the United States Food and Drug Administration to
20 be interchangeable with a specific biological product.

21 (f) The Board shall adopt rules for compliance with this
22 Section.

23 Section 99. Effective date. This Act takes effect July 1,
24 2016."